



IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of : **Confirmation No. 1343**
Yasumichi FUKUDA et al. : Attorney Docket No. 2006_1305A
Serial No. 10/590,871 : Group Art Unit 1614
Filed October 11, 2006 :
BICYCLO DERIVATIVE : THE COMMISSIONER IS AUTHORIZED
[Corresponding to PCT/JP2005/002806 TO CHARGE ANY DEFICIENCY IN THE
Filed February 22, 2005] FEE FOR THIS PAPER TO DEPOSIT
ACCOUNT NO. 23-0975.

SUBMISSION OF TRANSLATION OF
INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

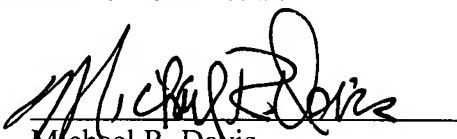
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants are submitting herewith a copy of Forms PCT/IB/338 and 373, together with a translation of the Written Opinion.

Respectfully submitted,

Yasumichi FUKUDA et al.

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April 27, 2007

PATENT COOPERATION TREATY

PCT/JP2005/002806

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

From the INTERNATIONAL BUREAU

HIKARI
PATENT OFFICE

OCT. 10. 2006

RECEIVED

To:

KISHIDA, Masayuki
Room 424, Marunouchi-Yaesu Building
6-2, Marunouchi 2-chome
Chiyoda-ku, Tokyo
1000005
JAPON

Date of mailing (day/month/year) 28 September 2006 (28.09.2006)	
Applicant's or agent's file reference FP0328PCT	IMPORTANT NOTIFICATION
International application No. PCT/JP2005/002806	International filing date (day/month/year) 22 February 2005 (22.02.2005)
Applicant KYORIN PHARMACEUTICAL CO., LTD. et al	

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference FP0328PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/JP2005/002806	International filing date (<i>day/month/year</i>) 22 February 2005 (22.02.2005)	Priority date (<i>day/month/year</i>) 27 February 2004 (27.02.2004)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant KYORIN PHARMACEUTICAL CO., LTD.		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;">Date of issuance of this report 19 September 2006 (19.09.2006)</td> </tr> <tr> <td style="padding: 2px;">Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int</td> </tr> </table>	Date of issuance of this report 19 September 2006 (19.09.2006)	Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int
Date of issuance of this report 19 September 2006 (19.09.2006)			
Authorized officer Yoshiko Kuwahara e-mail: pt07@wipo.int			

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

FP0328PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2005/002806

International filing date (day/month/year)

22.02.2005

Priority date (day/month/year)

27.02.2004

International Patent Classification (IPC) or both national classification and IPC

Applicant

KYORIN PHARMACEUTICAL CO., LTD.

I. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/002806

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/002806

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	2-4	YES
	Claims	1, 5-9	NO
Inventive step (IS)	Claims		YES
	Claims	1-9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO
2. Citations and explanations:			
<p>Document 1: US 2002/193390 A1 (Novartis A.G.), 19 December 2002</p> <p>Document 2: JP 2003-520849 A (Novartis A.G.), 08 July 2003</p> <p>[1] The inventions described in claims 1 and 5-9 do not appear to be novel or involve an inventive step based on document 1 cited in the ISR.</p> <p>Document 1 describes 1-[[N-(4-pentylbicyclo[2.2.2]oct-1-yl)amino]acetyl]-2-cyanopyrrolidine as a compound having DPP-IV inhibitory activity.</p> <p>[2] The inventions described in claims 1-9 do not appear to involve an inventive step based on documents 1 and 2 cited in the ISR.</p> <p>See above [1].</p> <p>The inventions described in claims 2-4 differ from the compounds described in document 1 in the point that a substituent for a 4-bicyclo[2.2.2] octane ring is a hydrogen atom, halogen atom and carboxyl group (see page 14, paragraph 0187).</p> <p>Identical to the compound described in document 1, document 2 describing a compound having DPP-IV inhibitory activity and containing a bicyclo[2.2.2] octane ring in an N(glycyl substitution)-2-cyanopyrrolidine skeleton describes, as a preferable compound, (S,S)1-(2-amino-2-bicyclo[2.2.2]oct-1-yl-acetyl)-2,5-dihydro-1H-pyrrol-2-carbonitrile (see page 32).</p> <p>Thus, not substituting a bicyclo[2.2.2] octane ring of the compound described in document 1 could be easily conceived of by a party skilled in the art.</p> <p>Also, document 2 (see claim 2 etc.) describes that a halogen atom and carboxyl group can be substituted for the ring; therefore, as a substituent for the bicyclo[2.2.2] octane ring described in document 1, conceiving of a compound containing a halogen atom and carboxyl group could be easily carried out by a party skilled in the art.</p>			